SUBMITTER INFORMATION

APR 24 2007

A.	Company Name:	Nidek Technologies Srl
B.	Company Address:	Via Dell'Artigianato, 6/A Albignasego (Padova), Italy 35020
C.	Company Phone: Company Fax:	+39 049 86 29 200 +39 049 86 26 824
D.	Contact Person:	Mr. Aldo Cocchiglia Managing Director Nidek Technologies Srl
E.	Date Summary Prepared:	January 18, 2007

DEVICE IDENTIFICATION

A.	Generic Device Name:	Ophthalmic camera, AC-powered
B.	Trade/Proprietary Name:	ORION
C.	Classification:	Class II
D.	Product Code:	HKI

DEVICE DESCRIPTION

The Nidek Technologies Srl ORION is an instrument for the diagnosis of retinal diseases. It is able to capture color images of the patient retina through CCD cameras.

The fundus camera ORION is supplied with Xenon light and IR LEDs sources suitable for performing the above described examinations.

The system includes also the dedicated NAVIS software (running with Windows XP e 2000 operative system).

INTENDED USE

ORION is intended for use as Fundus Camera. The color image of the fundus obtained in non-mydriatic conditions, using an IR sensible camera as a viewfinder and a visible flash for illuminating the retina at picture taking.

SUBSTANTIAL EQUIVALENCE

The Nidek Technologies Srl ORION device is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	510(K) Holder	510(k) No.	Date Cleared
MP-1 MICRO PERIMETER	NIDEK TECHNOLOGIES SRL	**K023719** **K061768**	12 / 23 / 2002 09 / 28 /2006
NON-MYDRIATIC FUNDUS CAMERA, MODEL NM-1000	NIDEK, INC	**K014274**	04/17/2002

In further support of a substantial equivalence determination, Section 5 provides a comparison chart of the fundus camera ORION and the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of ORION and the predicate devices has been performed. The results of this comparison demonstrate that the fundus camera ORION is equivalent to the marketed predicate devices.

PERFORMANCE DATA

The performance data indicate that the fundus camera ORION device meets all specified requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nidek Technologies, srl
c/o Aldo Cocchiglia
Via dell'Artigianato, 6/A
35020 Albignasego (Padova) Italy

APR 24 2007

Re: K070231
Trade/Device Name: ORION™
Regulation Number: 21 CFR 886.1120
Regulation Name: AC-Powered Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: April 2, 2007
Received: April 5, 2007

Dear Mr. Cocchiglia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070231

Device Name: ORION

Indications for Use: ORION is an ophthalmic camera that is indicated for use in capturing images of the retina.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K070231